SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4781-4800

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article in one case was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and in another case the label of the article bore the caution statement as quoted above, but the article was not one to which Section 503 (b) (1) applies.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4781. Mannitrau tablets and Serpenitrite tablets. (F. D. C. No. 37638. S. Nos. 4-317/8 M.)

QUANTITY: 1 34,000-tablet drum and 36 1,000-tablet btls. of *Mannitrau tablets* and 1 28,000-tablet drum of *Serpenitrite tablets* at Rochester, N. Y., in possession of William A. Straub.

SHIPPED: 12-7-54 and 12-16-54, from Philadelphia, Pa., by Riehlyn Laboratories.

LABEL IN PART: (Drum) "Special Formula * * * 'Mannitrau' * * * Each Tablet Contains: Phenobarbital 15 mg. * * * Mannitol Hex. 30 mg. Rauwolfia 50 mg. Rutin 20 mg. Caution: For Manufacturing, Processing or Repacking in the preparation of a new drug limited by Federal law to investigational use. * * * Richlyn Laboratories Philadelphia, Pa."; (btl.) "Mannitrau Mannitol Hexanitrate 30 mg. Rauwolfia Serpentina 50 mg. Rutin 20 mg. Phenobarbital 15 mg. * * * Use only as directed by a physician. Distributed by William A. Straub Rochester 9, New York"; (drum) "Special Formula * * * Each Tablet Contains: Rauwolfia Serpentina Pwd. Root 50 mg. Pwd. Extract Hyoscyamus 15 mg. Sodium Nitrite 50 mg. Pheno-

barbital 10 mg. Caution: For Manufacturing, Processing or Repacking in the preparation of a new drug limited by Federal law to investigational use. * * * Richlyn Laboratories Philadelphia, Pa."

RESULTS OF INVESTIGATION: The *Mannitrau tablets* in the bottles had been repackaged from the bulk drum and relabeled by the consignee. The *Serpenitrite tablets* were intended by the consignee to be repackaged into bottles labeled, in part, "Serpenitrite Rauwolfia Serpent. Po. Rt. 50 mg. Hyoscyamus Pwd. Extract 15 mg. Sodium Nitrite 50 mg. Phenobarbital 10 mg. * * * Use only as directed by a physician. Distributed by William A. Straub Rochester 9, New York."

Neither the Richlyn Laboratories nor William A. Straub had an effective new-drug application for the *Mannitrau tablets* or the *Serpenitrite tablets*.

LIBELED: 2–2–55, W. Dist. N. Y.

CHARGE: 505 (a)—the articles were new drugs within the meaning of the law, and no applications filed pursuant to the law were effective with respect to the articles.

DISPOSITION: 10–28–55. Default—destruction.

4782. Jel Royale tablets. (F. D. C. No. 38229. S. No. 9–550 M.)

QUANTITY: 24 100-tablet btls. and 7 500-tablet btls. at Los Angeles, Calif.

SHIPPED: 4–9–55, from San Antonio, Tex., by Howard Harmon.

LABEL IN PART: (Btl.) "Jel Royale Each Tablet Contains 0.5 mg. Queens' Jelly."

ACCOMPANYING LABELING: Brochures entitled "Is This your Fountain of Youth?"

RESULTS OF INVESTIGATION: The brochures were printed locally in Los Angeles, Calif.

LIBELED: 7–27–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was effective to delay age, restore sexual vigor, and promote growth; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–18–55. Default—destruction.

4783. Honey with Royal Jelly. (F. D. C. No. 38237. S. Nos. 9–553/4 M.)

QUANTITY: 12 cases, 24 12-oz. btls. each, at Los Angeles, Calif., in possession of Halco Corp.

SHIPPED: 4–28–55, from Weslaco, Tex., by Ault Bee Farms.

LABEL IN PART: (Btl.) "100% Pure Bee Ripened Honey * * * Fortified With 57.6 [or "5.76"] Grains Of That Wonder Food Queen's Royal Jelly and 5% Powdered Milk Recommended tablespoon [or "teaspoon"] daily."

ACCOMPANYING LABELING: Circulars entitled "The Queen's Jelly" and "On Honey, Royal Jelly and Natural Foods" and brochures entitled "The Story of 'Royal Jelly' and Peter."

LIBELED: 7–27–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article when shipped and while held for sale contained false and misleading representations that the